

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 16 NOV 2004		
Applicant's or agent's file reference 27359	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/IL04/00046	International filing date (day/month/year) 15 January 2004 (15.01.2004)	Priority date (day/month/year) 16 January 2003 (16.01.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 5/02 and US Cl.: 600/486, 485, 585		
Applicant		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

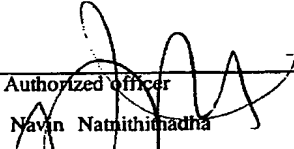
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Navin Natnithimadha Telephone No. (703) 308-1148
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL04/00046

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL04/00046

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>3, 7-23</u>	YES
	Claims <u>1, 2, 4-6</u>	NO
Inventive step (IS)	Claims <u>13-23</u>	YES
	Claims <u>1-12</u>	NO
Industrial applicability (IA)	Claims <u>1-23</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 2 and 4-6 lack novelty under PCT Article 33(2) as being anticipated by EINZIG '153.

In regards to claims 1 and 4, Einzig teaches a balloon catheter for detecting obstruction of blood flow within a blood vessel (see fig. 24 and col. 23, lines 25-35), comprising:

- a. a controllably inflatable balloon 128 (see fig. 12 and col. 18, line61);
- b. a first pressure sensor (optical fiber 118 terminating at sensitive zone 126 proximal of the balloon);
- c. a second pressure sensor (optical fiber 116 terminating at sensitive zone 122 distal of the balloon).

The method of claim 4 contains the same subject matter as claim 1 and is therefore rejected for the reason above.

As to claim 2, Einzig teaches the first and second pressure sensors report pressure measurements to a data receiver 326 by fiber optic wire connections.

As to claim 5, Einzig teaches monitoring two pressures, an abrupt narrowing in the vessel of finite length (stenosis) 410 is detected by observing a difference in the two pressures (see col. 23, lines 31-35).

As to claim 6, Einzig teaches determining the presence and location of stenosis by using pressure sensors (see col. 6, line 41-42).

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over EINZIG '153 in view of RINDNER '588.

As to claim 3, Einzig does not teach wireless pressure sensors. However, it is well known in the art at the time the invention was made to transmit pressure signals wirelessly. For example, Rindner teaches both wired and wireless means for transmitting pressure signals from the distal end of a catheter (see col. 2, lines 17-20).

Claims 8-12 lack an inventive step under PCT Article 33(3) as being obvious over EINZIG '153 in view of VAN WORMER '837.

As to claims 8-12, Einzig does not disclose determining the position of the balloon by an imaging modality such as an ultrasound system and using a radio-opaque marker. However, this is well known in the art at the time the invention was made. Van Wormer teaches determining a position of a balloon 10 on a catheter by using ultrasonic scanning of radio opaque markers 23, 24 (see fig. 2, col. 3, lines 52-56, and col. 4, lines 17-19).

Please See Continuation Sheet

**WRITTEN OPINION OF THE
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International application No.

PCT/IL04/00046

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 13 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: the claim ends with two periods.